



General

Guideline Title

Evaluation and treatment of cryptorchidism: AUA guideline.

Bibliographic Source(s)

Kolon TF, Herndon CD, Baker LA, Baskin LS, Baxter CG, Cheng EY, Diaz M, Lee PA, Seashore CJ, Tasian GE, Barthold J. Evaluation and treatment of cryptorchidism: AUA guideline. Linthicum (MD): American Urological Association Education and Research, Inc.; 2014 Apr. 38 p. [244 references]

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Definitions for the body of evidence strength (grade A, B, or C), the strength of the recommendations (Standard, Recommendation, Option), and for statements labeled as Clinical Principle and Expert Opinion are provided at the end of the "Major Recommendations" field.

Diagnosis

1. Providers should obtain gestational history at initial evaluation of boys with suspected cryptorchidism. (*Standard; Evidence Strength Grade B*)
2. Primary care providers should palpate testes for quality and position at each recommended well-child visit. (*Standard; Evidence Strength Grade B*)
3. Providers should refer infants with a history of cryptorchidism (detected at birth) who do not have spontaneous testicular descent by six months (corrected for gestational age) to an appropriate surgical specialist for timely evaluation. (*Standard; Evidence Strength Grade B*)
4. Providers should refer boys with the possibility of newly diagnosed (acquired) cryptorchidism after six months (corrected for gestational age) to an appropriate surgical specialist. (*Standard; Evidence Strength Grade B*)
5. Providers must immediately consult an appropriate specialist for all phenotypic male newborns with bilateral, nonpalpable testes for evaluation of a possible disorder of sex development (DSD). (*Standard; Evidence Strength Grade A*)
6. Providers should not perform ultrasound (US) or other imaging modalities in the evaluation of boys with cryptorchidism prior to referral as these studies rarely assist in decision making. (*Standard; Evidence Strength Grade B*)
7. Providers should assess the possibility of a disorder of sex development (DSD) when there is increasing severity of hypospadias with cryptorchidism. (*Recommendation; Evidence Strength Grade C*)
8. In boys with bilateral, nonpalpable testes who do not have congenital adrenal hyperplasia (CAH), providers should measure Müllerian

Inhibiting Substance (MIS or Anti-Müllerian Hormone [AMH]) level), and consider additional hormone testing, to evaluate for anorchia. (*Option; Evidence Strength Grade C*)

9. In boys with retractile testes, providers should monitor the position of the testes at least annually to monitor for secondary ascent. (*Standard; Evidence Strength Grade B*)

Treatment

10. Providers should not use hormonal therapy to induce testicular descent as evidence shows low response rates and lack of evidence for long-term efficacy. (*Standard; Evidence Strength Grade B*)
11. In the absence of spontaneous testicular descent by six months (corrected for gestational age), specialists should perform surgery within the next year. (*Standard; Evidence Strength Grade B*)
12. In prepubertal boys with palpable, cryptorchid testes, surgical specialists should perform scrotal or inguinal orchidopexy. (*Standard; Evidence Strength Grade B*)
13. In prepubertal boys with nonpalpable testes, surgical specialists should perform examination under anesthesia to reassess for palpability of testes. If nonpalpable, surgical exploration and, if indicated, abdominal orchidopexy should be performed. (*Standard; Evidence Strength Grade B*)
14. At the time of exploration for a nonpalpable testis in boys, surgical specialists should identify the status of the testicular vessels to help determine the next course of action. (*Clinical Principle*)
15. In boys with a normal contralateral testis, surgical specialists may perform an orchiectomy (removal of the undescended testis) if a boy has a normal contralateral testis and either very short testicular vessels and vas deferens, dysmorphic or very hypoplastic testis, or postpubertal age. (*Clinical Principle*)
16. Providers should counsel boys with a history of cryptorchidism and/or monorchidism and their parents regarding potential long-term risks and provide education on infertility and cancer risk. (*Clinical Principle*)

Definitions:

Body of Evidence Strength

Grade A: Well-conducted and highly-generalizable randomized controlled trials (RCTs) or exceptionally strong observational studies with consistent findings

Grade B: RCTs with some weaknesses of procedure or generalizability or generally strong observational studies with consistent findings

Grade C: Observational studies that are inconsistent, have small sample sizes, or have other problems that potentially confound interpretation of data

Note: By definition, Grade A evidence is evidence about which the Panel has a high level of certainty, Grade B evidence is evidence about which the Panel has a moderate level of certainty, and Grade C evidence is evidence about which the Panel has a low level of certainty.

American Urological Association (AUA) Nomenclature Linking Statement Type to Evidence Strength

Standard: Directive statement that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be taken based on Grade A or B evidence

Recommendation: Directive statement that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be taken based on Grade C evidence

Option: Non-directive statement that leaves the decision regarding an action up to the individual clinician and patient because the balance between benefits and risks/burdens appears equal or appears uncertain based on Grade A, B, or C evidence

Clinical Principle: A statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature

Expert Opinion: A statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge, and judgment for which there is no evidence

Clinical Algorithm(s)

An algorithm titled "Evaluation and Treatment of Cryptorchidism" is available from the [American Urological Association, Inc. \(AUA\) Web site](#)

Scope

Disease/Condition(s)

Cryptorchidism

Guideline Category

Diagnosis

Evaluation

Treatment

Clinical Specialty

Family Practice

Pediatrics

Surgery

Urology

Intended Users

Advanced Practice Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To provide physicians and non-physician providers (primary care and specialists) with a consensus of principles and treatment plans for the management of cryptorchidism

Target Population

Infants and boys with cryptorchidism

Interventions and Practices Considered

Diagnosis/Evaluation

1. Gestational history
2. Palpation of testes for quality and position
3. Referral to an appropriate surgical specialist
4. Ultrasound (not recommended)
5. Assessing the possibility of a disorder of sex development (DSD)

6. Müllerian Inhibiting Substance (MIS) measurement or other hormonal testing for bilateral anorchia
7. Annual evaluation of retractile testes

Treatment

1. Hormonal therapy to induce testis descent (not recommended)
2. Surgery (scrotal or inguinal orchidopexy for palpable testes)
3. Examination under anesthesia
4. Surgical exploration
5. Laparoscopic or abdominal orchidopexy for non-palpable testes
6. Counseling and education on infertility and cancer risk

Major Outcomes Considered

- Timely referral to specialists
- Sensitivity and specificity of diagnostic tests
- Rate of surgical complications
- Resolution (i.e., complete descent of the testes into the scrotum)
- Incidence of testicular cancer
- Incidence of impaired fertility
- Incidence of torsion and/or associated inguinal hernia

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The primary source of evidence for this guideline was the systematic review and data extraction conducted as part of the Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Review titled *Evaluation and Treatment of Cryptorchidism* (2012). That report included rigorous searches of MEDLINE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), and EMBASE for English-language studies published from January 1980 through February 2012 relevant to cryptorchidism. To capture more recently published manuscripts and expand the body of evidence provided in the original AHRQ report, the American Urological Association Education and Research, Inc. (AUA) conducted additional supplementary searches of PubMed and EMBASE for relevant articles published between January 1980 and March 2013 that were systematically reviewed using a methodology developed *a priori*.

Number of Source Documents

In total, these sources yielded 704 studies, after exclusions, that were used to inform the statements presented in the guideline as Standards, Recommendations or Options.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Body of Evidence Strength

Grade A: Well-conducted and highly-generalizable randomized controlled trials (RCTs) or exceptionally strong observational studies with consistent findings

Grade B: RCTs with some weaknesses of procedure or generalizability or generally strong observational studies with consistent findings

Grade C: Observational studies that are inconsistent, have small sample sizes, or have other problems that potentially confound interpretation of data

Note: By definition, Grade A evidence is evidence about which the Panel has a high level of certainty, Grade B evidence is evidence about which the Panel has a moderate level of certainty, and Grade C evidence is evidence about which the Panel has a low level of certainty.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Quality of Studies and Determination of Evidence Strength

Quality of individual studies was rated as high, moderate, or low based on instruments tailored to specific study designs. Randomized controlled trials (RCTs) were assessed using the Cochrane Risk of Bias tool. Conventional diagnostic cohort studies, diagnostic case-control studies, or diagnostic case series that presented data on diagnostic test characteristics were evaluated using the Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2) tool that evaluates the quality of diagnostic accuracy studies. Cohort studies with a comparison of interest were evaluated with the Drug Effectiveness Review Project instrument. The categorization of evidence strength is conceptually distinct from the quality of individual studies. Evidence strength refers to the body of evidence available for a particular question and includes consideration of study design, individual study quality, consistency of findings across studies, adequacy of sample sizes, and generalizability of samples, settings and treatments for the purposes of the guideline. The American Urological Association Education and Research, Inc. (AUA) categorizes body of evidence strength as Grade A (well-conducted RCTs or exceptionally strong observational studies), Grade B (RCTs with some weaknesses of procedure or generalizability or generally strong observational studies) or Grade C (observational studies that are inconsistent, have small sample sizes or have other problems that potentially confound interpretation of data). The quality of the evidence was variable depending on the issue examined. For many epidemiological issues there was a combination of moderate to large sized population-based studies, some of them prospective, being the key issue, as well as the consistency of findings. When evidence was consistent it was graded B, otherwise C. For issues related to management, studies tend to be non-randomized cohorts of moderate size or randomized trials of small to moderate size. Again the key issue was consistency of findings and the same criterion indicated above was applied. Seventy percent of the graded statements were considered level B (many under the AUA's premise of moderate quality, moderate certainty).

Limitations of the Literature

Limitations of the literature identified by both the Agency for Healthcare Research and Quality (AHRQ) and the AUA reviews include (1) lack of studies assessing the value of hormonal stimulation testing, long-term fertility outcomes, as well as inconsistent reporting of age at diagnosis and/or at treatment; (2) scant information about imaging effectiveness for modalities other than ultrasound (US) and magnetic resonance imaging (MRI); (3) low level evidence for the effectiveness of surgical treatment other than primary orchidopexy, accompanied by a lack of a standardized definition of success, follow-up length, reporting of complications, and control of confounding variables by indication; (4) inconsistent control of confounding variables among studies evaluating the epidemiology of cryptorchidism. This could be the result of the remaining uncertainty with respect to the etiological factors strongly and consistently associated with cryptorchidism.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

This document was written by the Cryptorchidism Panel of the American Urological Association Education and Research, Inc. (AUA), which was created in 2013. The Practice Guidelines Committee (PGC) of the AUA selected the committee chair. Panel members were selected by the chair. Membership of the committee included urologists and other clinicians with specific expertise on this disorder.

Linking Statement Type to Evidence Strength

The AUA nomenclature system explicitly links statement type to body of evidence strength and the Panel's judgment regarding the balance between benefits and risks/burdens (see the "Rating Scheme for the Strength of the Recommendations" field).

In some instances, the review revealed insufficient publications to address certain questions from an evidence basis; therefore, some statements are provided as *Clinical Principles* or as *Expert Opinions* with consensus achieved using a modified Delphi technique if differences of opinion emerged. A *Clinical Principle* is a statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature. *Expert Opinion* refers to a statement, achieved by consensus of the Panel that is based on members' clinical training, experience, knowledge and judgment for which there is no evidence.

Rating Scheme for the Strength of the Recommendations

American Urological Association (AUA) Nomenclature Linking Statement Type to Evidence Strength

Standard: Directive statement that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be taken based on Grade A or B evidence

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Clinical Principle: A statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature

Expert Opinion: A statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge, and judgment for which there is no evidence

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Peer Review

Description of Method of Guideline Validation

The American Urological Association Education and Research, Inc. (AUA) conducted an extensive peer review process. The initial draft of this Guideline was distributed to 84 peer reviewers of varying backgrounds, including those who applied through open comment; 43 responded with comments. The panel reviewed and discussed all submitted comments and revised the draft as needed. Once finalized, the Guideline was submitted for approval to the Practice Guidelines Committee (PGC). It was then submitted to the AUA Board of Directors for final approval. The Guideline was approved by the AUA Board of Directors in April 2014.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Where evidence was lacking, recommendations are supported by expert opinion or consensus.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate diagnosis and treatment of patients with cryptorchidism to optimize testis function, especially regarding fertility and cancer detection

Potential Harms

A potential complication resulting from surgical exploration can be inadvertent injury to the vas deferens or testicular vessels that could occur during surgical exploration, or there may be an erroneous diagnosis, although the risk of these unfavorable outcomes is very low.

Qualifying Statements

Qualifying Statements

- While these guidelines do not necessarily establish the standard of care, the American Urological Association Education and Research, Inc. (AUA) seeks to recommend and to encourage compliance by practitioners with current best practices related to the condition being treated. As medical knowledge expands and technology advances, the guidelines will change. Today these evidence-based guidelines statements represent not absolute mandates but provisional proposals for treatment under the specific conditions described in each document. For all these reasons, the guidelines do not pre-empt physician judgment in individual cases.
- Treating physicians must take into account variations in resources, and patient tolerances, needs, and preferences. Conformance with any clinical guideline does not guarantee a successful outcome. The guideline text may include information or recommendations about certain drug uses ("off label") that are not approved by the U.S. Food and Drug Administration (FDA), or about medications or substances not subject to the FDA approval process. AUA urges strict compliance with all government regulations and protocols for prescription and use of these substances. The physician is encouraged to carefully follow all available prescribing information about indications, contraindications, precautions and warnings. These guidelines and best practice statements are not intended to provide legal advice about use and misuse of these substances.
- Although guidelines are intended to encourage best practices and potentially encompass available technologies with sufficient data as of close of the literature review, they are necessarily time-limited. Guidelines cannot include evaluation of all data on emerging technologies or management, including those that are FDA-approved, which may immediately come to represent accepted clinical practices.
- For this reason, the AUA does not regard technologies or management which are too new to be addressed by this guideline as necessarily experimental or investigational.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Clinical Algorithm

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Patient-centeredness

Timeliness

Identifying Information and Availability

Bibliographic Source(s)

Kolon TF, Herndon CD, Baker LA, Baskin LS, Baxter CG, Cheng EY, Diaz M, Lee PA, Seashore CJ, Tasian GE, Barthold J. Evaluation and treatment of cryptorchidism: AUA guideline. Linthicum (MD): American Urological Association Education and Research, Inc.; 2014 Apr. 38 p. [244 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2014 Apr

Guideline Developer(s)

American Urological Association Education and Research, Inc. - Medical Specialty Society

Source(s) of Funding

Funding of the committee was provided by the American Urological Association, Inc. (AUA). Committee members received no remuneration for their work.

Guideline Committee

Cryptorchidism Panel

Composition of Group That Authored the Guideline

Panel Members: Thomas F. Kolon, MD (*Chair*), Children's Hospital of Philadelphia, Raymond and Ruth Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA; Peter A. Lee, MD, Penn State College of Medicine, Hershey, PA; Linda A. Baker, MD, Children's Medical Center J. Pavilion, Dallas, TX; Julia S. Barthold, M.D., FAAP (*Vice Chair*), duPont Hospital for Children, Wilmington, DE; Laurence S. Baskin, MD, ULSF Children's Hospital, San Francisco, CA; Cheryl G. Baxter, MSN, RN, CPNP, Nationwide Children's Hospital, NAPNAP, Columbus, OH; C.D. Anthony Herndon, MD, FAAP, FACS, University of Virginia Pediatric Urology, Charlottesville, VA; Earl Y. Cheng, MD, Lurie Children's Hospital of Chicago, Chicago, IL; Gregory E. Tasian, MD, MSc, MSCE, Center for Pediatric Clinical Effectiveness, Children's Hospital of Philadelphia, Philadelphia, PA; Carl J. Seashore, MD, FAAP, University of North Carolina, Chapel Hill, NC

Financial Disclosures/Conflicts of Interest

Conflict of Interest (COI) Disclosures

All panel members completed COI disclosures. Relationships that have expired (more than one year old) since the panel's initial meeting, are listed. Those marked with (C) indicate that compensation was received; relationships designated by (U) indicate no compensation was received.

Consultant or Advisor: Peter A Lee, Novo Nordisk (C), AbbVie, Inc. (C)

Meeting Participant or Lecturer: Earl Y. Cheng, Salix (C); Peter A Lee, Novo Nordisk (C), AbbVie, Inc. (C)

Scientific Study or Trial: Thomas F. Kolon, National Institutes for Health (NIH) (C); Julia S. Barthold: NIH (C); Earl Y. Cheng, NIH (U), Allergan (U); Peter A Lee, Novo Nordisk (C), AbbVie, Inc. (C)

Leadership Position: Peter A Lee, Pediatric Endocrine Society (U)

Other: Mireya Diaz, Henry Ford Hospital - Vattikuti Urology Institute (C)

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the [American Urological Association, Inc. \(AUA\) Web site](#) .

Availability of Companion Documents

The following is available:

- Person DF, Krishnaswami S, Jules A, Seroogy JC, McPheeters ML. Evaluation and treatment of cryptorchidism. Comparative Effectiveness Review No. 88 (prepared by Vanderbilt Evidence-based Practice Center under Contract No. 290-2007-10065-I). AHRQ Publication No. 13-EHC001-EF. Rockville (MD): Agency for Healthcare Research and Quality; 2012 Dec. 324 p. Electronic copies: Available from the [Agency for Healthcare Research and Quality Web site](#) .

The appendices to the original guideline document are available from the [American Urological Association, Inc. \(AUA\) Web site](#) .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on September 8, 2014. The information was verified by the guideline developer on

September 30, 2014.

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